

APPENDIX A: CONDITIONS FOR ASSESSMENT AND USE OF FEES

The FD&C Act, as amended by PDUFA, specifies three legal conditions that must be met each fiscal year for FDA to collect and spend prescription drug user fees. A summary of the legal conditions was introduced on page 2 of this report. This appendix provides detailed descriptions of these conditions and explanations of how FDA met these conditions in FY 2013.

To determine whether the legal conditions are satisfied, FDA must calculate and incorporate adjustment factors (defined in section 735(8) of the FD&C Act as amended) in the assessments of the first and third conditions. The FD&C Act states:

The term 'adjustment factor' applicable to a fiscal year is the Consumer Price Index for all urban consumers (all items, United States city average) for October of the preceding fiscal year divided by such Index for October 1996.

The consumer price index (CPI) for October 2011, the October of the fiscal year preceding FY 2013, was 226.421. The CPI for October 1996 was 158.3. Dividing the CPI of October 2011 by the CPI of October 1996 yields an adjustment factor of 1.430328 (rounded to the sixth decimal place) for FY 2013.

The **first legal condition** is found in section 736(f)(1) of the FD&C Act. It states that fees:

Shall be refunded for a fiscal year beginning after FY 1997 unless appropriations for salaries and expenses of the Food and Drug Administration for such fiscal year (excluding the amount of fees appropriated for such fiscal year) are equal to or greater than the amount of appropriations for the salaries and expenses of the Food and Drug Administration for the fiscal year 1997 (excluding the amount of fees appropriated for such fiscal year) multiplied by the adjustment factor applicable to the fiscal year involved.

The first condition requires that FDA's FY 2013 Salaries and Expenses Appropriation (excluding user fees and rent payments to GSA) be greater than or equal to FDA's Salaries and Expenses Appropriation (excluding user fees and rent payments to GSA) for FY 1997 multiplied by the adjustment factor for inflation. FDA's Salaries and Expenses Appropriation (excluding user fees and rent payments to GSA) for FY 1997 was \$819,971,000. Multiplying this amount by the adjustment factor of 1.430328 equals \$1,172,827,000 (rounded to the nearest thousand dollars).

In FY 2013, Congress appropriated \$2,347,014,000 to FDA for salaries and expenses, excluding user fees and rent payments to GSA. Because the FY 2013 Salaries and Expenses Appropriation is greater than the adjusted FY 1997 Salaries and Expenses Appropriation, \$1,172,827,000, the first legal condition was met.

The **second legal condition** is described in section 736(g)(2)(A)(i) and states that fees:

Shall be collected and available in each fiscal year in an amount not to exceed the amount specified in Appropriation Acts, or otherwise made available for obligation, for such fiscal year....

On March 26, 2013, the President signed the Consolidated and Further Continuing Appropriations Act, 2013, Public Law 113-6, which specified that \$718,669,000 shall be derived

from prescription drug user fees, and that prescription drug user fees collected in excess of this amount are also appropriated for FDA. Therefore, the second legal condition was met.

The **third legal condition** is defined in section 736(g)(2)(A)(ii); it states that fees:

Shall be available to defray increases in the costs of the resources allocated for the process for the review of human drug applications (including increases in such costs for an additional number of full-time equivalent positions in the Department of Health and Human Services to be engaged in such process) over such costs, excluding costs paid from fees collected under this section, for fiscal year 1997 multiplied by the adjustment factor.

The third condition requires a minimum spending from appropriations, excluding user fees, on the process of human drug application review. The minimum spending from appropriations is the amount that FDA spent on the process for the review of human drug applications in FY 1997, multiplied by the adjustment factor.

In FY 1997, the amount spent from appropriations on the process for the review of human drug applications was \$147,959,689. After applying the adjustment factor of 1.430328 (rounded to sixth decimal place), the minimum appropriation spending level for the process for the review of prescription drug applications for FY 2013, excluding user fees, is \$211,631,000 (rounded to the nearest thousand dollars).

In FY 2013, FDA obligated \$299,267,407 from appropriations, exclusive of user fees, for the process for the review of human drug applications, which exceeds the specified minimum appropriation spending level. Therefore, the third legal condition was met.